

Application Serial No. 10/675,147
Filed September 30, 2003
Amendment dated July 16, 2007
Confirmation No. 5607
Attorney Docket No. SERE-06

REMARKS

Claims 1-27 are pending in the application. Claims 1-27 are rejected.

Claims 13, 14, 19, 22, 25, and 27 are presently amended. Applicant submits herewith a Declaration of Gilbert R. Gonzales under 37 C.F.R. § 1.132 dated July 13, 2007 ("Declaration"). In view of the amendments, the Declaration, and the discussion below, Applicant respectfully submits that the rejections of the claims have been overcome and the application is now in condition for allowance.

Summary of the Invention of the Present Application

The effective administration of medications for the treatment of disease symptoms and for the alleviation of pain, i.e., pain management, is an important aspect to the overall treatment of patients for both curable diseases and terminal illnesses. Oral administration has been widely used for dispensing pain medications such as narcotic and non-narcotic analgesics. However, oral administration is oftentimes not possible due either to obstruction of the oral and gastrointestinal tract or to severe nausea. Further, parenteral administration, including intravenous administration (e.g., IV drips), has been used for long-term administration of medication in controlled dosages. However, parenteral administration is invasive and usually painful to the patient. Further, parenteral administration is also not practical for long-term patient care because terminally ill patients may not have the physical capability of performing the injection procedure, and if physically able, may not have the knowledge to properly

choose an injection site. Thus, multiple appointments with medical personnel are required.

Thus, rectal administration of medications has become widely used for administering a number of different medications in order to overcome the drawbacks of oral and parenteral/intravenous administration. In this method, medications are absorbed through the rectal mucous membranes. However, there are drawbacks with this type of administration, as well, and thus there is need for further improvement for methods of pain management.

These drawbacks have been overcome by the invention of the present application, which includes an infusor system for administering medications to a patient through an indwelling venous needle or venous catheter. This needle or catheter is placed into a superficial vein or veins of the pelvic or inguinal region. A supply of medication is delivered into a tube, and from the tube into the IV needle or indwelling catheter. This system eliminates the large expenses associated with the above-described procedures, which involve administration and continual monitoring by professional medical personnel. The medications dispensed through the infusor system are rapidly and efficiently absorbed into the necessary areas of the body for alleviation of the medical condition or the pain associated therewith.

Further, medications can be delivered into the intraspinal regions through an indwelling needle or catheter. As medication is dispensed, intraabdominal pressure

is increased, such as by utilizing an abdominal restraint or binder. The blood flow in the vertebral venous plexus (Batson's plexus) is reversed, and the dispensed medication is delivered from the rectal veins directly into the vertebral bones, the epidural and intrathecal space, and the spinal cord.

Therefore, the infusor system of the present invention provides a more direct infusion of medication, either continuously or in bolus dosages, into the spinal cord and other vertebral structures as compared to previous oral, parenteral, or rectal administration, for more effective pain management.

Claim Rejections 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claim 27 under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. In particular, the Examiner states that claim 27 omits the step of actually administering medication to a patient. The preamble of originally filed claim 27 was directed to "[a] method of administering medications to a patient," whereas the body of claim 27 listed a method of aspirating or sampling venous blood. And so, in response, Applicant has presently amended the preamble of claim 27 to be directed to a "method of aspirating or sampling venous blood." In view of this amendment and in view of the fact that the method of claim 27 recites, "aspirating or sampling venous blood," Applicant submits that the rejection under 35 U.S.C. § 112, second paragraph, has been overcome, and thus requests withdrawal of the rejection.

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Claim Rejections 35 U.S.C. § 103

Gonzales/Winchell/Brennan

The Examiner has rejected claims 1-24 and 26 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,846,216 (Gonzales) in view of U.S. Patent No. 5,061,243 (Winchell) or U.S. Patent No. 4,941,875 (Brennan). The Examiner states that Gonzales discloses an infusor system for administering medications including a flexible elongated delivery tube, a supply of liquid medication, a delivery component, a pressure-altering device, and the administration of drug to venous blood vessels. The Examiner acknowledges that Gonzales does not disclose the administration of medication directly into a venous blood vessel (such as through a venous needle), but points to Winchell and Brennan as teaching the use of a venous needle for delivering medications. Therefore, the Examiner suggests that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Gonzales with the teachings of Winchell or Brennan in order to provide a means for entering a blood vessel so that a direct supply of medication can be provided. More specifically, the Examiner suggests that replacing the rectal delivery head of Gonzales with IV administration, as shown in Brennan or Winchell, would have been obvious to one skilled in the art. Applicant respectfully disagrees.

In concluding why one skilled in the art would consider such a modification obvious, the Examiner states, "The advantages of utilizing direct delivery via a

needle/catheter rather than going through a membrane are well known in the art."

Applicant submits that this may be true in the standard venous system, but it is not true in Batson's plexus, which is one of many venous plexuses and one of the few true isolated plexuses of the body (the others being the plexus around the esophagus, and the plexus that includes the interior carotid for the eye). (See Declaration, paragraph 10). There are various reasons for this. For example, the plexuses are often very poorly anatomically defined. (See Declaration, paragraph 10). And so, the vessels that comprise Batson's plexus or communicate with Batson's plexus are also poorly defined. (See Declaration, paragraph 10). Second, Batson's plexus is variable from person to person in terms of the veins that comprise the plexus or communicate with the plexus (i.e., vein "X" may communicate with Batson's plexus in patient "A," but not in patient "B"). (See Declaration, paragraph 10). So, until Applicant developed the claimed invention, no one knew, in an individual human, how many and which veins, if any, were actually useful for delivering medication via Batson's plexus. (See Declaration, paragraph 10). This problem, however, does not present itself with the rectal mucous membrane delivery of Gonzales, since medication that is transported across the rectal mucous membranes cross-communicates with all veins in the region, thereby resulting in medication being delivered to the intraspinal region in any patient in which it is tried. (See Declaration, paragraph 10).

And so, with such direct venous delivery thought to be impossible, Applicant did not include it in Gonzales (as Applicant is a named inventor on Gonzales). (See Declaration, paragraph 11). No one knew of direct venous delivery that could be performed usefully until Applicant determined and described the direct communication of veins in the present '147 Application. (See Declaration, paragraph 11). Thus, even though the teachings of Gonzales, Brennan, and Winchell were known, that knowledge would have been useless to anyone who wanted to deliver medication in Batson's plexus via direct vein delivery. (See Declaration, paragraph 11). In other words, even if one were to replace the rectal dispenser head of Gonzales with a catheter (or needle, or other delivery component), one still could not deliver medications to the intraspinal region because that individual would not know where to insert the catheter. (See Declaration, paragraph 11). Thus, an individual skilled in the art, and armed with the knowledge of the cited references, would not replace the rectal dispenser head of Gonzales because to do so would result in no medication reaching the intraspinal region, whereas the dispenser head would result in medication reaching the intraspinal region. (See Declaration, paragraph 11). As such, at the time, there were no advantages in utilizing direct delivery via a needle/catheter rather than going through a membrane. Quite the contrary, utilizing direct delivery via a needle/catheter would have been disadvantageous.

In fact, if such a change was so advantageous, why was it not done before the presently claimed invention (especially given the numerous advantages that would obtain through direct vein catheterization)? In 1940, Oscar Batson first described the plexus, and taught that the dorsal vein of the penis could communicate with the plexus. (See Declaration, paragraph 12). However, Batson taught that the dorsal vein of the penis was the only vein that could allow such delivery. (See Declaration, paragraph 12). From 1940 until the '147 Application, there had only been one other study that elucidated a vein that could communicate with Batson's plexus. (See Declaration, paragraph 12). That study was performed by Applicant, and determined that the dorsal vein of the tail in rats communicated with the plexus. (See Declaration, paragraph 12). However, neither of these two veins is useful in delivering medication in humans. First, humans do not have a dorsal vein of the tail (since humans do not have a tail). Second, any attempted delivery of drug via the dorsal vein of the penis is not feasible, especially in the non-erectile penis, and such delivery is not possible in women.

Thus, from 1940 (when Batson first described the plexus) until Applicant's work, which resulted in the '147 Application being filed in 2003, nobody could deliver medication into the intraspinal region via direct vein catheterization and using the reversal of blood flow in Batson's plexus (a span of 63 years). (See Declaration, paragraph 13). So, until Applicant developed the claimed invention, including the communication of the particular veins with Batson's plexus recited in the present claims,

no one had, or would have had, any idea that venous delivery would work or could work. If Batson or others after him (although there have been none until Applicant, and until the presently claimed invention) could have anticipated another venous route other than the dorsal vein of the penis, Applicant believes that it would have been tried and/or used by Batson and many other anatomists/surgeons due to the many advantages that would obtain. (See Declaration, paragraph 13).

For example, catheterization of the pudic family of veins allows the patient to be upright and ambulatory during the dispensing of medication. (See Declaration, paragraph 14). This contrasts with the rectal dispenser head mucous membrane infusion of Gonzales, wherein a patient must remain recumbent during the dispensing of medication. (See Declaration, paragraph 14). Further, previous drugs that could not be infused rectally (for example, those with structure too large to cross the rectal mucous membranes) can now be administered by delivery via the pudic family of veins. (See Declaration, paragraph 14). Further, massive drug deliveries can be given through catheterization of the pudic family of veins. (See Declaration, paragraph 14). The rectal dispenser head mucous membrane infusion method exhibits an across-the-membrane rate limiting effect, which requires relatively potent drugs to be delivered (due to the relatively low volume per time of infusion). (See Declaration, paragraph 14). However, through a system including IV delivery via the pudic family of veins, one can deliver high volumes of low potency drugs. (See Declaration, paragraph 14). And further, because

the pudic family of veins directly communicates with Batson's plexus (to the exclusion of any cross-communication with other vessels), medications may be delivered directly to Batson's plexus without the medication being diluted by diversion to other vessels. (See Declaration, paragraph 14). In the previous rectal dispenser head mucous membrane infusion of Gonzales, drugs could not be focused to particular veins (such as the pudic family of veins), and thus would also enter vessels having cross-communication with other vessels of the body. (See Declaration, paragraph 14). Given all these advantages, Applicant submits that if catheterization of the pudic family of veins, and thus IV delivery of medication to the intraspinal region via reversal of blood flow in Batson's plexus were obvious, it certainly would have been done previously.

In view of the above, Applicant respectfully submits that the rejection of claims 1-24 and 26 under 35 U.S.C. § 103(a) as obvious over Gonzales in view of Winchell or Brennan is in error, and requests that it be withdrawn.

Gonzales/Winchell/Brennan/Lynn

The Examiner has rejected claims 25 and 27 under 35 U.S.C. § 103(a) as being unpatentable over Gonzales in view of Winchell or Brennan in further view of U.S. Patent No. 5,549,569 (Lynn). The Examiner acknowledges that Gonzales does not explicitly disclose the sampling or aspirating of venous blood, but points to Lynn as teaching the sampling or aspirating of venous blood. Therefore, the Examiner suggests that it would have been obvious to one of ordinary skill in the art at the time of the

invention to modify the method of Gonzales with the teachings of Lynn in order to obtain blood samples for further testing. Applicant respectfully disagrees.

As an initial matter, Applicant notes that claim 25 simply depends from independent claim 13 (which was rejected over Gonzales in view of Winchell or Brennan -- as discussed above). Claim 25 merely adds that "the delivery tube is further inserted up into the vertebrovenous plexus region." As claim 25 does not include any recitation to aspirating or sampling venous blood, Applicant believes that the Examiner likely meant to reject it along with claim 13 over Gonzales in view of Winchell or Brennan.

Regardless, Applicant notes that both claims 25 and 27 recite a venous blood vessel chosen from a pudic vein, an internal pudic vein, and an external pudic vein. As described above, Applicant submits that one skilled in the art would not have replaced the rectal dispenser head of Gonzales with the venous delivery taught in Winchell or Brennan, because to do so would have rendered the delivery of medications via Batson's plexus inoperative. Like Winchell and Brennan, Lynn does disclose a venous needle or catheter. However, for the same reasons discussed above with respect to Winchell and Brennan, if one skilled in the art would have replaced the rectal dispenser head of Gonzales with the venous needle or catheter of Lynn, one would not then have known where to insert that venous needle or catheter. Thus, Applicant submits that Lynn does not cure any of the defects described above with respect to the

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combination of Gonzales with Winchell or Brennan. And so, Applicant respectfully submits that it would not have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Gonzales with the teachings of Lynn in order to obtain blood samples for further testing, because such modification would have rendered such a method inoperative.

In view of the above, Applicant respectfully requests withdrawal of the rejection of claims 25 and 27 under 35 U.S.C. § 103(a) as obvious over Gonzales in view of Winchell or Brennan in further view of Lynn.

Conclusion

For the foregoing reasons, it is submitted that all claims are patentable, and a Notice of Allowance is respectfully requested.

No fee is believed due. Any deficiencies or credits necessary to complete this communication should be applied to Deposit Account No. 23-3000.

The Examiner is invited to contact the undersigned attorney with any questions or remaining issues.

Respectfully submitted,
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